DEPARTMENT OF HEALTH AND HUMAN SERVICE

946692

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
Facsimile 504-253-4520

April 30, 2004

WARNING LETTER NO. 2004-NOL-25

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Allen J. Estay, Owner
Blue Water Shrimp Company Inc.
8624 Grand Caillou Road
Dulac, Louisiana 70353

Dear Mr. Estay:

We inspected your firm, located at 8624 Grand Caillou Road, Dulac, Louisiana, on February 11 - 12, 2004, and found that you have serious deviations from the Seafood Hazard Analysis Critical Control Point (HACCP) regulation, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123) and the Food Labeling regulations, 21 CFR 101. These deviations cause your ready-to-eat Bowfin roe to be in violation of Sections 402(a)(4) and 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The Seafood HACCP deviations were as follows:

- You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for Bowfin roe caviar lists a monitoring procedure at the "[redacted]" critical control point that is not adequate to control pathogen growth, specifically *Clostridium botulinum*. Your monitoring procedures list "[redacted]" at a frequency of "[redacted]." These monitoring procedures and frequencies do not clearly explain your methods for monitoring the amount of salt versus the amount of roe by weight which enables you to attain your critical limit of [redacted] salt. For example, the amount [redacted] can vary based on the total weight of roe, therefore, adjustments in the quantity of salt would be necessary to attain a minimum of [redacted] in larger quantities.

  Your finished product roe is frozen immediately after processing; however, if maintained frozen throughout distribution, and labeled prominently with instructions to hold frozen and to thaw under refrigeration immediately before use (e.g. "Important, Keep Frozen, Thaw Under Refrigeration Immediately Before Use"), it would not be necessary to have controls in place for *Clostridium botulinum*.

- You must implement the record keeping system that you listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the "Receiving" and "[redacted]" critical control points to control pathogen growth as listed in your HACCP plan for Bowfin roe caviar.

- Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate to comply with 21 CFR 123.7(b). However, your corrective action plan for Bowfin roe at the "[redacted]" critical control point is not appropriate. Ensuring that the salt is fully dissolved cannot assure that a [redacted] salt critical limit is achieved in all instances, nor does the corrective action address the cause of the deviation or ensure that unsafe goods do not enter commerce.

- You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records for safety of the water that comes into contact with food or food contact surfaces; condition and cleanliness of food contact surfaces; prevention of cross-contamination; maintenance of hand washing, hand sanitizing, and toilet facilities; protection of food, food packaging material, and food contact surfaces from adulteration with contaminants; proper labeling, storage, and use of toxic compounds; control of employee health conditions that could result in microbiological contamination; and, exclusion of pests from the food plant required for the processing of ready-to-eat Bowfin roe caviar.

A review of your product label for "North American Black Caviar" reveals a deviation from the food labeling requirements. This deviation causes your product to be misbranded within the meaning of Section 403(i)(2) in that the label fails to bear an ingredient statement. In the case where a food is fabricated from two or more ingredients, the common or usual name of each ingredient shall be declared in the ingredient statement (21 CFR 101.4); for example, Bowfin caviar, salt. In addition, the name "caviar" unqualified should only be applied to Sturgeon roe. Caviar prepared from the roe of other fish, i.e. Bowfin, must be labeled to show the name of the fish from which it is prepared; for example, Bowfin caviar.

We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your product and/or enjoin your firm from operating.

We are aware that during our inspection Ms. Dawn M. Estay, Secretary/Treasurer, made a verbal commitment to correct violations observed at your firm. However, you must respond in writing, within fifteen (15) working days from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies and to assure that such violations will not recur. You may wish to include in your response documentation such as your revised finished product labels, HACCP plan, sanitation monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulation, and the Current Good Manufacturing Practice regulation, 21 CFR 110. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4514.

Sincerely,

Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483